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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,913	10/05/2001	Richard T. Smith	2105.2210	3137

5514 7590 07/29/2003

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EXAMINER

CONLEY, SEAN E

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 07/29/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/970,913

Applicant(s)

SMITH ET AL.

Examiner

Sean E Conley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on February 11, 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed May 5, 2003 has been received and considered for examination. Claims 1-77 are pending and claims 1, 13, 24, 33-65, 70 and 75 have been amended.

Claim Rejections - 35 USC § 112

2. Claims 1-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims have been amended to include the limitation "the sterilant being maintained in a completely vapor state". There is no support for this limitation in the applicant's specification.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taggart (U.S. Pat. 6,209,591 B1).

Taggart discloses a method and apparatus for providing a container product

filling in an aseptic processing apparatus. The apparatus and method meets the stringent United States FDA (Food and Drug Administration) requirements and 3A Sanitary standards and Accepted Practices required to label a food product (foodstuffs) as "aseptic". In addition, the apparatus produces a packaging material with at least about a 6 log reduction of *Bacillus subtilis* var. *globigii* spores using a hydrogen peroxide sterilant vapor with a concentration of about 35% (see column 4, lines 25-41).

More specifically, the invention of Taggart processes containers such as bottles or jars that have a small opening compared to its height and its greatest width (e.g. the ratio of the opening diameter to the height of the container is less than 1.0). In the preferred embodiment, a bottle **12** is formed of a plastic such as polyethylene terephthalate (PET). The aseptic sterilant that is used by Taggart is selected from hydrogen peroxide or oxonia, with hydrogen peroxide being the preferred sterilant (see column 4, lines 42-55 and figure 8).

The process delivers the empty bottles to a filler apparatus **50** after passing through a bottle infeed and sterilization apparatus **60** for aseptic sterilization. The bottles **12** in the conveying plate **94** enter an interior bottle sterilization apparatus **116**. A heated hydrogen peroxide vapor fog is introduced into the interior **118** of each bottle **12** (see figures 3 and 10). The application of the sterilant is accomplished with the use of a plurality of sterilant measuring devices **121** and a plurality of probes **123**. Each probe **123** includes an applicator spray nozzle **122**, which provides uniform sterilant application without droplet formation on the interior surface **119** of the bottle **12** (see column 8, lines 17-50). It can be seen in figure 10 that the spray nozzle **122** is

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positioned through an opening in the container and located just below the shoulder of the bottle and the nozzle has a diameter no great than one-half the diameter of the opening **16**. Also, figure 10 shows that the nozzle **122** is inserted within $1/6$ and $5/6$ the height of the container.

Furthermore, Taggart discloses that a direct spray of heated hydrogen peroxide may be continuously applied to the outside surface **34** of each bottle **12**. A spray nozzle produces the direct spray and a heat exchanger heats the hydrogen peroxide above its vaporization point (see column 6, lines 20-33). Additionally, the probe **123** including the applicator spray nozzles **122** may be positioned immediately above the bottle openings prior to the application of the sterilant (see column 10, lines 28-43).

After the step of applying the hydrogen peroxide vapor to the interior **118** of the bottles **12** the sterilant is purged from the bottles. The purging process introduces a heated gas into the interior of the bottles at a temperature of 131° F and for a time period of about 24 seconds (see column 12, lines 28-67). The temperature is selected based upon the heat resistance for PET bottles and that generally is about 55° C (131° F). The PET bottles may deform when exposed to temperatures above 131° F for extended periods of time. After the bottle is dried, the residual hydrogen peroxide remaining on the bottle **12** surface is less than 0.5 ppm (see column 12, lines 65-67).

The entire process is controlled by a control system **550**, which monitors and controls a spray apparatus **126** that includes the probe **123** and the applicator spray nozzles **122** (see figures 10, 13 and column 10, line 29-42).

The reference to Taggart does not specifically disclose or recite that the nozzle is positioned no closer than 15 mm from any internal surface of the container that is perpendicular to a principal direction of flow of the sterilant vapor from the nozzle.

However, it would have been obvious to one of ordinary level of skill in the art to insert the nozzle into the container and position the nozzle a predetermined optimum distance away from the surfaces being sterilized in order to prevent droplet formation of hydrogen peroxide on the interior surfaces and furthermore, it would have been obvious in view of figure 10 which shows that the nozzle 122 is inserted through the opening 16 of the bottle 12 and is located a distance from the interior surfaces of the bottle.

Also, the reference does not teach a method of removing *Bacillus subtilis* var. *globigii* and *Saccharomyces cerevisiae* spores wherein the reduction by a predetermined amount X (log) and Y (log) is effected by the equations recited in the applicants claims 65, 68, 70 and 73.

However, the reference to Taggart teaches a 6 log reduction of *Bacillus subtilis* var. *globigii* spores as required by the applicant and Taggart also teaches the same parameters (temperature and concentration) for hydrogen peroxide sterilization and purging of PET bottles. Therefore, it would have been obvious to one of ordinary level of skill in the art to determine any remaining parameters such as container size, mass of sterilant and humidity in order to sterilize PET bottles because Taggart discloses achieving a 6 log reduction of *Bacillus subtilis* var. *globigii* spores in PET bottles using hydrogen peroxide vapor as claimed by the applicant. Furthermore, it would have been obvious to determine the optimum parameters of temperature, mass of sterilant,

humidity, and container volume to sterilize for other organisms that are not taught by Taggart.

Applicant's Arguments

5. The applicant argues that Taggart fails to disclose or suggest the use of a sterilant vapor, the sterilant vapor being maintained in a completely vapor state.
6. The applicant argues that Taggart fails to disclose or suggest effecting a reduction of microorganisms by controlling the vapor generating, vapor discharging and purging steps so as to satisfy the equations of independent claims 65 and 70.
7. The applicant argues that Taggart fails to recognize the hydrogen peroxide trapping problem with the sterilization/sanitation of PET containers. Taggart does not disclose or suggest that 24 hours after the purging step, hydrogen peroxide residual in non-heat-set PET containers should be (or is) less than the 0.5 ppm limit required by the FDA. Accordingly, Taggart also fails to disclose or suggest reduction of the sterilant in the PET container to a predetermined amount $Z(\text{mg/l})$ at 24 hours after the purging step by satisfying the equation recited in independent claim 75.
8. The applicant argues that Taggart does not teach a nozzle located just below the shoulder of the bottle.

Response to Arguments

9. Applicant's arguments filed May 7, 2003, with respect to the rejection(s) of claim(s) 1-74, have been fully considered but they are not persuasive.

First, the applicant's disclosure does not provide support for maintaining the hydrogen peroxide sterilant in a completely vapor state. Taggart does in fact teach the use of a hydrogen peroxide vapor sterilant. It is disclosed in column 6, lines 14-33, that the hydrogen peroxide liquid sterilant is sprayed into an air stream and atomized and then heated to a point above its vaporization phase. Thus, the hydrogen peroxide sterilant is in a vapor state when it is applied to the container surfaces.

Additionally, the Merriam-Webster dictionary defines vapor as diffused matter (as smoke or fog) suspended floating in the air and impairing its transparency. Fog is considered to be a vapor and therefore, a hydrogen peroxide vapor fog is hydrogen peroxide in a vapor state.

Furthermore, even if Taggart did not teach a hydrogen peroxide sterilant in a completely vapor state, it would have been obvious to use a hydrogen peroxide sterilant in a completely vapor state based on the applicant's admitted state of the prior art. The applicant disclosed on page 2, lines 2-5, that the known apparatuses and methods often use a sterilant such as hydrogen peroxide vapor. After hydrogen peroxide vapor is discharged into the container at relatively high temperature, the residual sterilant is then purged from the container with a hot air flush at high temperature.

Regarding the applicants arguments of independent claims 65 and 70, the examiner maintains that it would have been obvious to one of ordinary level of skill in

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the art to determine parameters such as container size, mass of sterilant and humidity in order to sterilize PET bottles because Taggart discloses achieving a 6 log reduction of *Bacillus subtilis* var. *globigii* spores in PET bottles using hydrogen peroxide vapor as claimed by the applicant, thus achieving the same results. Furthermore, it would have been obvious to determine the optimum parameters of temperature, mass of sterilant, humidity, and container volume to sterilize for other organisms that are not taught by Taggart. The general conditions of the claim are disclosed in Taggart and discovering the optimum or workable ranges involves only routine skill in the art.

Regarding the applicant's argument that Taggart does not teach a nozzle located just below the shoulder of the bottle, the examiner maintains that fig. 10 has been interpreted to show that the nozzle is located below the should of the container. Additionally, Taggart discloses that the applicator nozzles descend into the interior toward the bottom of the bottles. This ensures the complete application of sterilant to the entire interior surface of the bottle (see column 10, lines 28-42). Furthermore, it would have been obvious to reposition the nozzle inside the container depending on the shape of the container to be sterilized in order to maximize the sterilization of the interior surfaces.

10. Applicant's arguments, filed May 7, 2003, with respect to the rejection(s) of claim(s) 75-77 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, the claims are still rejected

under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. 6,120,730 to Palaniappan et al.

Palaniappan et al. Teaches a method of sterilizing PET bottles using a hydrogen peroxide gas.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Conley, whose telephone number is (703) 305-2430. The examiner can normally be reached on Monday-Friday 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Robert Warden, can be reached at (703) 308-2920. The Unofficial fax phone number for this group is (703) 305-7719. The Official fax phone number for this Group is (703) 872-9310.

When filing a FAX in Technology Center 1700, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite the processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [robert.warden@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, whose telephone number is (703) 308-0661.

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SEC *Ac*

July 24, 2003

Robert J. Warden, Sr.

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